IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Navin Natnithithadha
Art Unit	:	3736
Applicants	:	Richard J. Melker and David Bjoraker
Serial No.	:	10/054,619
Filed	:	January 22, 2002
Conf. No.	:	5786
For	:	Method and Apparatus for Monitoring Intravenous (IV) Drug Concentration Using Exhaled Breath

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RICHARD J. MELKER, M.D. UNDER 37 CFR 1.132

Sir:

I, Richard J. Melker, hereby declare:

THAT, I am a co-inventor of the subject matter claimed in U.S. patent application Serial No. 10/054,619 (hereinafter the '619 application);

THAT, a copy of my curriculum vitae is attached hereto;

THAT, I have reviewed the Office Action mailed April 8, 2003 in the '619 application along with the references cited therein;

And, being thus duly qualified, do further declare as follows:

At the time that Littlejohn (U.S. Patent No. 3,659,199) issued, unconsciousness (anesthesia) was maintained during most surgeries using potent inhalation anesthetics. In certain instances, anesthesiologists elected to use the less potent inhalation agent, nitrous oxide. However, using nitrous oxide required major supplementation with narcotics, benzodiazepines, or other intravenous hypnotic drugs. (The remainder of procedures was performed with local or regional anesthesia.) Satisfactory intravenous anesthetic agents that could be used independently as the entire anesthetic,

such as propofol, had not yet been developed. With the discovery of propofol and its introduction in the 1980's, total intravenous anesthesia (TIVA), became increasingly popular, especially for office-based surgery.

Today, almost 50% of all anesthetics administered in Europe are with TIVA, and in certain settings in the United States, almost all anesthetics, and often conscious sedation, use TIVA as well. Despite the popularity of TIVA, only indirect monitoring with systems that process electrical activity from the brain has been developed. Also, despite the popularity of using exhaled gas to measure carbon dioxide concentration, and concentration of anesthetic agents such as nitrous oxide, halothane, and other potent inhalation agents, there has been no suggestion in either the medical literature, intellectual property, or in clinical care to use exhaled gas to monitor or predict the blood concentration, and therefore the anesthetic effect of drugs such as propofol that are not administered via inhalation. This is clearly demonstrated by the time that has passed since the issuance of the Littlejohn patent and the time that has passed since the introduction of propofol. Yet, until the subject '619 application, there is no disclosure by anyone of monitoring the anesthetic concentration of drugs not administered by inhalation through the analysis of exhaled gas.

The undersigned declares further that all statements made herein of his or her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or of any patent issuing thereon.

Further declarant sayeth naught.

Signed: _____
By: Richard J. Melker

Date: July 8, 2003

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Education:
M.D., Albert Einstein College of Medicine, 1974
Ph.D., Albert Einstein College of Medicine, Neurobiology, 1973
M.S., New York University, Neurobiology, 1970

Professional Experience:
University of Florida, College of Medicine, Anesthesiology, Professor Appointed: 1996
University of Florida, College of Engineering, Biomedical Engineering, Professor Appointed: 1998
University of Florida, College of Medicine, Pediatrics, Professor Appointed: 1996

Funding Received:
Development of a Neural Network Controlled Ventilator, $1,000,050 (subcont), from Sep 2002 to Aug 2003
Evaluation of pulse oximeter probes, $50,000, from Oct 1998 to Mar 1999
Effect of Warm Fluids of Peripheral Venous Resistance, $13,000, from May 1, 2000 to Jul 31, 2000
Real-time MR evaluation of inhaled drug delivery systems, $720,000, from May 2002 to Apr 2004
MR Evaluation of Inhaler Devices, $43,000, from May 2000 to Oct 2000
Report on the use of biomedical technology in the delivery of alternative site healthcare, $80,000, from Mar 1997 to Sep 1997
A Glucose Meter Part-task Trainer for Children, $20,000, from Jun 1, 2000 to May 31, 2001
Development of Specifications for the Next Generation Hill-Rom CarePorter, $45,500, from Jun 1, 1999 to Sep 30, 1999
Development of a Part-task Trainer User Interface, $15,000, from Jun 1, 1999 to May 31, 2000
MRI Study of the Dynamic Motion of the Human Trachea, $23,000, from Jun 1999 to Sep 1999
Patient Compliance Breath Feedback System, $100,000, from Jul 1, 2000 to Dec 31, 2000
Joint development of an interactive communications and monitoring system for remote patient care, $350,000, from Jul 1996 to Oct 1997
Evaluation of a prototype demand-flow valve, $5,175, from Jul 1992 to Jun 1993
Research and development of transportable ventilators and monitoring systems, $302,400, from Jul 1992 to Jun 1996
A model for the study of acid-base balance and ventilation in low blood flow states, $32,623, from Jul 1991 to Jun 1992
Development and evaluation of IDLH ventilators, $13,000, from Jul to Jun
Conforming cuffless endotracheal tube agreement, $131,261, from Jul to Dec 1996
Development of a Neural Network Controlled Ventilator, $20,000, from Jan 1, 2001 to Dec 31, 2001

Electronic gas blender, $75,255, from Jan 1995 to Jan 1997
Development of the method for light and sound conduction through the trachea, $17,000, from Jan 1995 to Dec 1995
Bioengineering Research Partnership for Brain Dynamics, $5,373,000, from Dec 1, 2001 to Nov 30, 2006
Endowment for ventilator research and development, $158,125, from 1995 to 1996

Publications:

- Melker RJ. The Institute of Medicine report on medical errors [letter]. New England Journal of Medicine. 343(9): 664-5, Aug 2000
- Gravenstein D, Melker RJ, Lampotang S. Clinical assessment of a plastic optical fiber stylet for human tracheal intubation. Anesthesiology. 91(3): 648-53, Sep 1999
- Cardoso MM, Banner MJ, Melker RJ, Bjoraker DG. Portable devices used to detect endotracheal intubation during emergency situations: a review. Critical Care Medicine. 26(5): 957-64, May 1998
- Idris AH, Becker LB, Fuerst RS, Wenzel V, Rush WJ, Melker RJ, Orban DJ. Effect of ventilation on resuscitation in an animal model of cardiac arrest. Circulation. 90(6): 3063-9, Dec 1994
- Idris AH, Staples ED, O'Brien DJ, Melker RJ, Rush WJ, Del Duca KD, Falk JL. Effect of ventilation on acid-base balance and oxygenation in low blood-flow states. Critical Care Medicine. 22(11): 1827-34, Nov 1994
- Idris AH, Banner MJ, Wenzel V, Fuerst RS, Becker LB, Melker RJ. Ventilation caused by external chest compression is unable to sustain effective gas exchange during CPR: a comparison with mechanical ventilation. Resuscitation. 28(2): 143-50, Oct 1994
- Idris AH, Staples ED, O'Brien DJ, Melker RJ, Rush WJ, Del Duca KD, Falk JL. End-tidal carbon dioxide during extremely low cardiac output. Annals of Emergency Medicine. 23(3): 568-72, Mar 1994
- Melker RJ. The making of a physician. Pharos of Alpha Omega Alpha Honor Medical Society. 56(4): 34, 1993
- Idris AH, Melker RJ. High-flow sheaths for pediatric fluid resuscitation: a comparison of flow rates with standard pediatric catheters. Pediatric Emergency Care. 8(3): 119-22, Jun 1992
- Melker RJ. Saphenous vein cutdown. American Journal of Emergency Medicine. 8(2): 176-7, Mar 1990
- Melker RJ. Alternative methods of ventilation during respiratory and cardiac arrest. Circulation. 74(6 Pt 2): IV63-5, Dec 1986
- Melker RJ. Intraosseous infusions. American Journal of Emergency Medicine. 4(5): 490, Sep 1986
- Melker RJ. Recommendations for ventilation during cardiopulmonary resuscitation: time for change?. Critical Care Medicine. 13(11): 882-3, Nov 1985
- Melker RJ, Banner MJ. Ventilation during CPR: two-rescuer standards reappraised. Annals of Emergency Medicine. 14(5): 397-402, May 1985
- Melker RJ. Asynchronous and other alternative methods of ventilation during CPR. Annals of Emergency Medicine. 13(9 Pt 2): 758-61, Sep 1984
- Cavallaro DL, Melker RJ. Comparison of two techniques for detecting cardiac activity in infants. Critical Care Medicine. 11(3): 189-90, Mar 1983
- Krischer JP, Melker RJ, Barkalow CE. A programmable resuscitator for evaluation of CPR standards. Medical Instrumentation. 14(1): 51-3, 1980
- Melker RJ, Gordon AS. The esophageal obturator airway. Chest. 76(5): 611-4, Nov 1979

- Melker RJ. Removal of aspirated tracheal foreign bodies. Journal of Pediatrics. 93(4): 722-4, Oct 1978
- Waxman SG, Melker RJ. Closely spaced nodes of Ranvier in the mammalian brain. Brain Research. 32(2): 445-8, Sep 1971

Patent Information:

- Method for improving lung delivery of pharmaceutical aerosols, United States, 6,567,686, 2003, Industry-owned
- Method, System and Apparatus for Medical Device Training, United States of America, 6535714, 2003, Institution-owned
- Method and Apparatus for Controlling a Medical Ventilator, United States of America, 6390091 B1, 2002, Licensed
- Imaging Scope, United States, 6,322,498, 2001, Institution-owned
- Imaging Scope, United States of America, 6115523, 2000, Institution-owned
- Patient Data Acquision and Communication System, United States of America, 6074345, 2000, Licensed
- Medical Device using Hydrogel Materials, United States of America, Allowed, 2000, Institution-owned
- Materials and methods utilizing a temporary visual indicator, United States of America, 6139821, 2000, Licensed
- Transtracheal energy application and sensing system for intubation: method and apparatus, United States of America, 6161537, 2000, Institution-owned
- Hybrid Microprocessor Ventilator Unit, United States of America, 6000396, 1999, Institution-owned
- Novel materials and methods utilizing a temporary visual indicator, United States of America, 5997891, 1999, Licensed
- Intraosseous needle, 5601559, 1998, Licensed
- Intraosseous Needle Assemby, Canada, 2001214, 1998, Licensed
- Gas blender, United States, 5,887,611, 1998, Institution-owned
- Materials and methods utilizing a temporary visual indicator, United States of America, 5837645, 1998, Licensed
- IV administration apparatus, United States of America, 5599303, 1997, Self-owned
- Universal ventilation device, United States of America, 5628305, 1997, Self-owned
- Intraosseous Needle, EP49051B1, 1996, Licensed
- Intraosseous needle, United States of America, 5484442, 1996, Licensed
- Novel materials and methods utilizing a temporary visual indicator, United States of America, 5523075, 1996, Licensed
- Novel materials and methods utilizing a temporary visual indicator: An indicator sunscreen, United States of America, 5532029, 1996, Licensed
- Transtracheal energy application and sensing system for intubation: method and apparatus, United States of America, 5560351, 1996, Institution-owned
- Introducer Sheaths, EP593181A3, 1995, Licensed
- Intraosseous Needle, EP439516B1, 1995, Licensed
- Intraosseous needle assembly, United States of America, 5431655, 1995, Licensed
- Introducer Sheaths, EP593181A2, 1994, Licensed

- Intraosseous needle assembly, Australia, 641825, 1994, Licensed
- Sharp instrument encapsulation system, United States of America, 5322165, 1994, Licensed
- Vascular wire guide introducer and method of use, United States of America, 5328480, 1994, Licensed
- Wireless high flow sheath, United States of America, 5242410, 1993, Institution-owned
- High flow multilumen introducer sheath, United States of America, 5250038, 1993, Licensed
- Arterial/venous fluid transfer system, United States of America, 5203771, 1993, Institution-owned
- Arterial/venous fluid transfer system, United States of America, 5135492, 1992, Institution-owned
- Needle shielding fluid transfer device, United States of America, 5158558, 1992, Institution-owned
- Emergency cricothyrotomy system and cricothyrotomy kit, United States of America, 4677978, 1987, Licensed

Honors and Awards Information:

- 1998, Second Place for Scientific Exhibit, International Anesthesia Research Society
- 1997, Honorable Mention for Scientific Exhibit, New York State Society of Anesthesiologists, Postgraduate Assembly of Anesthesiology
- 1997, Ellison C. Pierce Award for Best Scientific Exhibit on Patient Safety, American Society of Anesthesiologists
- 1990, Best Content and Significance to Emergency Medicine, Florida ACEP
- 1974, Alpha Omega Alpha (Member)

Membership Information:

Alpha Omega Alpha